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COGNIS CORPORATION  
PATENT DEPARTMENT  
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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/762,895

Applicant(s)

ANDERSON ET AL.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/17&amp;6/24/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' Preliminary amendment filed 22 January 2004 is acknowledged and entered.
2. Please note that the correct application number for your instant application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) is 10/762,895, not "Continuation Under 37 C. F.R. §1.53(b) of Application Serial No. 09/663,963 filed 09/19/2000 as noted in the header for the Preliminary amendment to Claims filed 22 January 2004. To expedite the prosecution of the instant application and in correlating any papers for the instant application please ensure that all further correspondence regarding the instant application has the correct application number (i.e., 10/762,895).
3. Please note that the correct filing date for the instant application is 22 January 2004.
4. Your instant application under prosecution at the USPTO is assigned to Art Unit 1655. To expedite the prosecution of the instant application and in correlating any papers for the instant application please ensure that all further correspondence regarding the instant application is directed to Art Unit 1655.
5. The assigned Examiner to your application under prosecution at the USPTO is Dr. Kailash C. Srivastava. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.

### **Claims Status**

6. Claims 1-13 are cancelled.
7. Claim 14 has been amended.
8. Claims 14-28 are pending and are examined on merits.

### **Priority**

9. Applicants' claim for domestic priority under 35 U.S.C. § 119(e) to Provisional U.S. Application Serial Number 60/334,463 filed 30 November 2001 is acknowledged.
10. Applicants' claim for domestic priority under 35 U.S.C. § 120 to Provisional U.S. Application Serial Number 60/156,791 filed 30 September 1999 and under 35 U.S.C. § 121 to Non-provisional U.S. Application, serial Number 09/663,963 filed 19 September 2000, now abandoned is acknowledged.

### Information Disclosure Statement

11. Applicants' Information Disclosure Statements (i.e., IDSs) filed 17 March, and 14 June 2004 have been made of record and considered.

### Objection To Claims – Minor Informalities

12. Claims 15-28 are objected to because of the following informalities:

- Claims 15-28 each are objected to because at Line one of each one of the cited Claims, before the word "wherein" a --, -- should be inserted.
- In Claim 14step (d), the phrase, "fermenting the organism" is inappropriate. The fermentation liquid or culture medium is fermented, not the organism.

Appropriate correction is required.

### Objection to Abstract

13. The abstract of the disclosure in this application does not truly represent the claimed invention. The abstract describes a composition (i.e., a culture medium), not a method whereas the invention is drawn to a method. Appropriate correction is required. Applicants are warned to be careful to not add any new matter while revising the abstract for suggested correction(s).

### Claim Rejections - 35 USC § 102/103

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless –*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

17. Claims 14, 17-26 and 28 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Shirai et al (U.S. patent 5,618,708).

Claims recite a method to produce a color and odor-stable polyol in a culture medium comprising a substrate, carbon and energy source (e.g., glucose), a source of inorganic nitrogen (e.g., ammonium sulfate), potassium phosphate, calcium, a trace metal, an antifoam, a chelating agent and an additional limitation of source of inorganic nitrogen selected from the group "consisting of ammonium, hydroxide, and mixtures thereof".

Shirai et al., disclose a method to produce inositol (i.e., a polyol) in a culture medium comprising glucose, ammonium sulfate, vitamin, potassium phosphate, calcium chloride, sodium chloride, copper, iron, zinc and other trace elements, citric acid (i.e., a chelant), additional inorganic nitrogen sources as gaseous ammonia and an antifoam (Column 5, Lines 65-68 and Column 6, Lines 1-32). Note that Shirai et al., inherently teach a color and odor-stable polyol because the reference teaches a method to produce a polyol according to the same steps and applying same medium components as are instantly claimed, Thus, Shirai et al. teach a method to produce a polyol in a culture medium comprising an organic carbon/energy source, an inorganic nitrogen source, a metal salt, potassium phosphate, a chelant (citric acid) biotin or a source of biotin (biotin, See, Column 7, Table 2). That is the reference teaches a method to produce same material in a culture medium comprising the same components that are recited in the instantly claimed invention.

However, even if the reference and the claimed invention are not one and the same and there is, in fact, no anticipation, the reference method would, nevertheless, have rendered the claimed method obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the products produced and the components of the culture medium employed to produce said product in said method.

Thus the claimed invention at the time that said invention was made, as a whole was clearly *prima facie* obvious, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

***A person shall be entitled to a patent unless –***

***(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.***

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

21. Claims 14-22 and 24-26 are rejected under 35 U.S.C. §102(a) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Mobley et al (U.S. Patent 6,066,480) with evidence provided by Takahashi et al., 1965, Applied Microbiology, Volume 13, Pages 1-4).

Claims recite a method to produce a color and odor-stable polycarboxylic acid in a culture medium comprising a substrate, a carbon and energy source (e.g., glucose), a source of inorganic nitrogen (e.g., ammonium sulfate), potassium phosphate, calcium, a trace metal, and antifoam.

Mobley et al., disclose a method to produce  $\alpha,\omega$ -alkane dicarboxylic acid (i.e., a polycarboxylic acid) in a culture medium comprising glucose, ammonium sulfate, vitamin, potassium phosphate, calcium chloride, sodium chloride, copper, iron, zinc and other trace elements, antifoam (see Table 2), additionally an alkane as a substrate and *Candida tropicalis* as the organism (Abstract, Lines 1-12). Note that Mobley et al., inherently teach a color and odor-stable polycarboxylic acid because the reference teaches a method to produce a polycarboxylic acid (i.e.,  $\alpha,\omega$ -alkane dicarboxylic acid) according to the same steps and applying same medium components, wherein the organism is *Candida tropicalis*, as is instantly claimed. Thus, Mobley et al. teach a method (Abstract, Lines 1-12; Column 3, Lines 57-67; Column 4, Lines 1-16; Column 5, Lines 5-28; Column 8, Lines 19-68; Table 2 and Column 10, Line 55 to

Column 11, Line 41) to produce a polycarboxylic acid in a culture medium comprising an alkane substrate, an organic carbon/energy source, an inorganic nitrogen source, a metal salt, potassium phosphate, a source for biotin (i.e., corn steep liquor (See Takahashi et al. Applied Microbiology, 1965, Pages 1-4, Abstract). That is, the reference teaches a method to produce same material in a culture medium comprising the same components that are recited in the instantly claimed invention.

However, even if the reference and the claimed invention are not one and the same and there is, in fact, no anticipation, the reference method would, nevertheless, have rendered the claimed method obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the products produced and the components of the culture medium employed to produce said product in said method.

Thus, the claimed invention at the time that said invention was made as a whole was clearly *prima facie* obvious, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

In this rejection under 35 U.S.C. §§102(a)/103(a), Takahashi et al., (1965, Applied Microbiology, Volume 13, Pages 1-4) is cited to merely support that biotin is an integral components of corn steep liquor and other nutrient components (e.g., yeast extract) that are generally applied in the microbiological culture media as a source of nitrogen and/or carbon, and said reference is not cited as a prior art reference.

### ***Claim Rejections - 35 USC § 103***

22. Claims 14-28 are rejected under 35 U.S.C. § 103(a) as obvious over the combination of Shirai et al (U.S. patent 5,618,708) in view of Mobley et al (U.S. Patent 6,066,480) with evidence provided by Takahashi et al. (Applied Microbiology, 1965. Volume 13, Pages 1-4)

Claims recite a method to produce a color and odor-stable polyol or polycarboxylic acid in a culture medium comprising a substrate, carbon and energy source (e.g., glucose), a source of inorganic nitrogen (e.g., ammonium sulfate), potassium phosphate, calcium, a trace metal, an antifoam, a chelating agent and an additional limitation of source of inorganic nitrogen selected from the group "consisting of ammonium, hydroxide, and mixtures thereof", wherein the organism is *Candida tropicalis*.

Teachings from each, Shirai et al (U.S. patent 5,618,708) and Mobley et al (U.S. Patent 6,066,480) with evidence provided by Takahashi et al. (Applied Microbiology, 1965, Pages 1-4) have been already discussed *supra*.

Shirai et al. does not teach the control of dissolved oxygen and explicitly does not teach that antifoam is an integral component of the culture medium wherein *Candida tropicalis* is cultivated in the method to produce polycarboxylic acid. Mobley et al. explicitly teach a method to produce polycarboxylic acid from alkane substrates in a culture medium comprising antifoam, wherein organism is *Candida tropicalis*. Mobley et al. extendedly discuss the importance of dissolved oxygen and low concentrations of dissolved oxygen to achieve higher yield of the product after a good growth of the microorganism is achieved in a culture medium comprising high concentrations of dissolved oxygen.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Shirai et al's teachings according to Mobley et al's beneficial teachings to obtain a method to produce a polycarboxylic acid/polyol in a culture medium comprising a substrate, carbon and energy source (e.g., glucose), a source of inorganic nitrogen (e.g., ammonium sulfate), potassium phosphate, calcium, a trace metal, an antifoam, a chelating agent and an additional limitation of source of inorganic nitrogen selected from the group "consisting of ammonium, hydroxide, and mixtures thereof", wherein the organism is *Candida tropicalis*, because Mobley et al teach a method to produce polycarboxylic acid in a culture medium comprising same components as those taught by Shirai et al, and additionally/explicitly teach that the culture medium contains an antifoam, an alkane substrate and *Candida tropicalis* as the organism. The concentrations of different components of the culture medium disclosed in the prior art references are precisely not the same as claimed instantly. However, the adjustment of particular conventional working conditions (e.g., choice of equivalence for a pH, reagents, ionic strengths etc.) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter that is well within the purview of the skilled artisan.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Shirai et al's teachings according to Mobley et al's beneficial teachings to obtain a method to produce a polycarboxylic acid/polyol in a culture medium comprising a substrate, carbon and energy source (e.g., glucose), a source of inorganic nitrogen (e.g., ammonium sulfate), potassium phosphate, calcium, a trace metal, an antifoam, a chelating agent and an additional limitation of source of inorganic nitrogen selected from the group "consisting of ammonium, hydroxide, and mixtures thereof", wherein the organism is *Candida tropicalis*, because as discussed above, Mobley et al. remedy the deficiencies in the teachings from Shirai et al.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore,



the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Claim Rejections - 35 U.S.C. § 112***

23. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.***

24. Claim 15 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim is directed to *C. tropicalis* organism.

25. The *C. tropicalis* organism should be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, a deposit of the microorganism in a recognized depository may satisfy the requirements of 35 U.S.C. §112.

Furthermore, in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR §1.807 which states:

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

- (1) The name and address of the depository;
- (2) The name and address of the depositor;
- (3) The date of deposit;
- (4) The identity of the deposit and the accession number given by the depository;
- (5) The date of the viability test;
- (6) The procedures used to obtain a sample if the test is not done by the depository; and
- (7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR §1.809(d) which states:

(d) For each deposit made pursuant to these regulations, the specification shall contain:

- (1) The accession number for the deposit;
- (2) The date of the deposit.

26. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

27. Claims 14-28 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- The recitation "capable of " renders Claim 14 indefinite because this recitation in and by itself denotes a futuristic event. The metes and bounds of the claimed subject matter are not clearly defined. The examiner suggests that the applicants define the metes and bounds of the term "capable of".
- Claim 15 is unclear by the abbreviation "C." Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.
- The recitation "metabolizable " renders Claim 17 indefinite because this recitation in and by itself denotes a futuristic event. The metes and bounds of the claimed subject matter are not clearly defined. The examiner suggests that the applicants define the metes and bounds of the term "metabolizable".

All other claims depend directly from the rejected claims (e.g., Claim 3) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.


### Conclusion

28. For reasons aforementioned, no Claims are allowed.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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June 26, 2006



CHRISTOPHER R. TATE  
PRIMARY EXAMINER